REMARKS

This is responsive to the Office Action mailed February 18, 2009. Reconsideration and allowance of claims 1-11, 13, 15, 16, and 18-30 as set forth herein are requested.

Status of the claims

Claims 1-27 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Li et al., U.S. Pat. No. 6,836,529 (hereinafter "Li") in view of Forbes et al., U.S. Pat. No. 5,913,308.

Claims 1-27 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Li in view of Forbes in further view of Sivard, U.S. Pat. No. 5,355,894 (hereinafter "Sivard").

The applied references

Li relates primarily to cardiac-gated imaging. The only two mentions of respiratory monitoring in Li is in the abstract ("A system and method of diagnostic imaging with reduced x-ray exposure to the scan subject during scanning includes acquiring a set of cardiac signals or other motion (cardiac mechanical motion or respiratory motion) related signals and determining and imaging profile therefrom.") and at col. 5 lines 44-47 ("While EKG signals have heretofore been described as a means of developing an imaging profile, other data signals may be acquired and analyzed to develop an imaging profile including respiratory data signals.").

Li does not disclose the system or method by which the "respiratory data signals" are generated. Indeed, Li provides no information whatsoever about how one performs respiratory monitoring. For example, the "respiratory data signals" of Li could be acquired using a pneumotach which measures the flow of air with a tube through which the subject breathes, or using a mechanical strain gauge or other mechanical sensor. *See* Forbes col. 1 lines 26-32.

Forbes discloses techniques for extracting a respiratory muscle tremor (RMT) from an electrocardiogram (ECG) signal. As discussed in Forbes, performing respiratory monitoring by deriving a respiratory signal from the ECG signal is

difficult, because the ECG signal is dominated by the cardiac cycling with respiration being only a secondary influence on the ECG signal. Forbes col. 1 lines 32 ff.

Sivard discloses a respiratory monitor disposed in a cardiac pacemaker. To implement the pacemaker function (that is, to stimulate the heart in order to maintain rhythmic cardiac cycling, one electrode is disposed in the heart of the patient and the other electrode is connected to a housing of the pacemaker, and a stimulation pulse generator (1) delivers pacemaker pulses. Sivard col. 3 lines 38-44. The cardiac pacemaker functionality is further implemented by a pacemaker controller (6) and an impedance measuring unit (7) that generates a test current and measures the voltage drop to determin impedance, and sends the measured impedance output to a unit (13) that determines respiration volume per unit time. Sivard col. 3 lines 44-64. The output of the unit (13) is fed back to the controller (6) to control the stimulation pulse output based on respiration. Sivard col. 3 lines 64-68.

The claims present patentable subject matter

and should be allowed

Claim 1 as amended recites a pair of electrodes adapted to *externally* contact a thoracic region of the subject; an electrical meter that measures a time-varying electrical parameter across the electrode pair *by applying a voltage or current pulse train having a frequency substantially higher than the heart rate across the pair of electrodes*; and a monitor that extracts a time-varying respiration characteristic from the measured time-varying electrical parameter. The addition by amendment of *externally* finds support in the original specification at least in Fig. 1 which illustrates external electrodes (30, 32) that are also ECG electrodes. The amendment reciting applying a voltage or current pulse train having a frequency substantially higher than the heart rate across the pair of electrodes finds support in the original specification at least at page 5 lines 5-8.

The Office Action recognizes that neither Li nor Forbes, nor their combination, disclose or fairly suggest applying a voltage or current to the subject. Office Action page 4. Sivard discloses applying a test current to a stimulation electrode (4). However, this electrode (4) is disposed *in the heart* (Sivard col. 3 line 41), and hence is not an electrode adapted to *externally* contact a thoracic region. The

second electrode (5) of Sivard is connected to a heart pacemaker housing (Sivard col. 3 lines 42-44), and hence is not even adapted to contact a thoracic region, much less to *externally* contact a thoracic region.

Claim 1 is directed to diagnostic imaging system including a diagnostic imaging scanner that acquires imaging data of a subject in an examination region. The *internal* electrodes (4, 5) of Sivard are not conducive for use in such a diagnostic imaging system, since the skilled artisan certainly does not want to perform open heart surgery on the subject to install the electrodes prior to acquiring imaging data.

Conversely, although Forbes discloses monitoring respiratory muscle tremor (RMT) using external ECG electrodes, Forbes does so using a completely different technique from that of Sivard. Forbes relies upon processing the passive ECG signal, rather than employing a technique that includes applying a voltage or current to the subject. There is no reason the skilled artisan would expect the respiratory monitoring of Sivard, which employs an electrode arranged *in the heart* of the subject, to work with the external ECG electrodes of Forbes.

Further, claim 1 recites an electrical meter that measures a time-varying electrical parameter across the electrode pair *by applying a voltage or current pulse train having a frequency substantially higher than the heart rate* across the pair of electrodes. Neither Li nor Forbes, nor their combination, disclose or fairly suggest applying a voltage or current to the subject. Sivard discloses applying a test current to the stimulation electrode (4) (Sivard col. 3 line 53), but does not disclose or fairly suggest that this test current be a current *pulse train having a frequency substantially higher than the heart rate*. The present application (*not* Sivard) explains that by using such a pulse train "the impedance measurement signal and the electrocardiographic signal are readily decoupled by frequency selective filtering." Present application page 5 lines 6-8.

In this regard it should be noted that the stimulation pulses generated by Sivard's stimulation pulse generator (1) are used for *regulating the cardiac cycling*, as per usual operation of a *heart pacemaker*. The stimulation pulses stimulate the heart beat so as to regulate the heart rate. Sivard does not disclose or fairly suggest using these stimulation pulses for respiratory monitoring, and indeed to the contrary affirmatively discloses using a *separate test current* for this purpose.

Claim 4 depends from claim 1, and recites a *voltage* pulse generator that applies a *voltage* pulse train to the electrode pair. Sivard discloses using a test *current* for respiratory monitoring, not a test voltage.

New claim 30 depends from claim 1 and recites the electrical meter applies the voltage or current pulse train having a frequency in the tens of kilohertz range. This claim finds support in the original specification at least at page 5 lines 13-14. Nothing in Sivard suggests its test current is a current pulse train, much less a current pulse train having a frequency in the tens of kilohertz.

Claim 13 is amended to incorporate subject matter recited in dependent claims 14 and 17, and is further amended to specify *externally* contacting a thoracic region of the patient with the pair of *external* electrodes. This latter amendment finds support in the original specification at least in Fig. 1 which illustrates external electrodes (30, 32) that are also ECG electrodes.

The Office Action recognizes that neither Li nor Forbes, nor their combination, disclose or fairly suggest applying a voltage or current to the subject. Office Action page 4. The Office Action relies upon Sivard as disclosing this feature.

Sivard does indeed disclose that the impedance measuring unit (7) applies a test current at prescribed times for the purpose of measuring an impedance that is used by the unit (13) to identify respiration volume per unit time. Sivard col. 3 lines 52-64. However, the electrodes in Sivard are not external electrodes, but rather include a return electrode (5) connected to a housing of a heart pacemaker (which is implanted in the patient) and a stimulation electrode (4) arranged *in the heart* of the patient. Sivard col. 3 lines 40-44. Neither of these electrodes (4, 5) are external electrodes, and furthermore the return electrode (5) is not contacting a thoracic region of the patient (rather, it contacts the pacemaker housing).

Li and Forbes cannot cure these deficiencies of Sivard. Li does not disclose any sort of respiratory monitoring method. Forbes discloses respiratory monitoring using external electrodes, but discloses a wholly different monitoring method in which respiratory muscle tremor (RMT) is extracted from a passive ECG signal. There is no basis for the skilled artisan to conclude that the method of Sivard, which employs an electrode *in the heart* of the patient, could possibly work using an *external* electrode.

Claim 19 depends from claim 13 and further recites measuring cardiac cycling data using the external pair of electrodes. Forbes employs electrodes for both RMT monitoring and ECG monitoring. However, Forbes' RMT monitoring employs the *same passive ECG signal* for both RMT monitoring and cardiac cycling data. The Office Action acknowledges that Forbes does not disclose or fairly suggest applying a voltage or current to the subject. Office Action page 4. Sivard discloses using the electrode (4) for both respiratory monitoring and for *applying* the *stimulation* pulses which *affirmatively control* the cardiac cycling (that is what a pacemaker does). Sivard does *not* use the electrode (4) for *measuring* cardiac cycling data.

New claim 29 depends from claim 13 and further recites the applying comprises applying a pulse train of voltage or current pulses having a pulse frequency substantially higher than the heart rate to the electrodes pair. This claim find support in the original specification at least at page 5 lines 5-8, where it is explained that in this way "the impedance measurement signal and the electrocardiographic signal are readily decoupled by frequency selective filtering." Present application page 5 lines 6-8. Of the applied references, only Sivard discloses applying any sort of voltage or current at all (i.e., the "test current") and Sivard does not disclose applying a pulse train, much less a pulse train having a pulse frequency substantially higher than the heart rate.

Claim 18 has been placed into independent form including the limitations of original base claims 13 and 17. It is respectfully submitted that the scope of claim 18 is not affected by this amendment.

Claim 18 recites measuring a time-varying electrical parameter across an electrodes pair during the acquiring of imaging data, the measuring including *applying a pulse train of voltage or current pulses to the electrodes pair*, measuring the other of voltage and current responsive to the applying, and computing the time-varying electrical parameter based on the applied and measured quantities; and computing a time-varying respiration characteristic based on the measured time-varying electrical parameter.

The Office Action recognizes that neither Li nor Forbes, nor their combination, disclose or fairly suggest applying a voltage or current to the subject. Office Action page 4. The Office Action relies upon Sivard as disclosing this feature.

Sivard discloses a stimulation pulse generator (1) for generating stimulation pulses applied to the stimulation electrode (4). Sivard col. 3 lines 38-44. This is the pacemaker operation of the heart pacemaker, that is, the stimulation pulses stimulate the heart to beat in a desired rhythmic pattern.

These stimulation pulses are *not* used in computing the time-varying electrical parameter based on the applied and measured quantities, and are *not* used in computing a time-varying respiration characteristic based on the measured time-varying electrical parameter

Sivard discloses that the impedance measuring unit (7) applies a test current at prescribed times for the purpose of measuring an impedance that is used by the unit (13) to identify respiration volume per unit time. Sivard col. 3 lines 52-64.

Accordingly, Sivard does not disclose or fairly suggest *applying a pulse train of voltage or current pulses to the electrodes pair*, measuring the other of voltage and current responsive to the applying, and *computing a time-varying electrical parameter based on the applied and measured quantities*; and *computing a time-varying respiration characteristic* based on the measured time-varying electrical parameter. Nor would it be obvious to do so, even in combination with Li and Forbes. Li discloses no respiration monitoring whatsoever, while Forbes discloses respiration monitoring based on a passive ECG signal.

New claim 28 depends from claim 18 and further recites the applying a pulse train of voltage or current pulses to the electrodes pair comprises applying a pulse train of voltage or current pulses having a pulse frequency substantially higher than the heart rate. This claim find support in the original specification at least at page 5 lines 5-8, where it is explained that in this way "the impedance measurement signal and the electrocardiographic signal are readily decoupled by frequency selective filtering." Present application page 5 lines 6-8. Of the applied references, only Sivard discloses applying any sort of voltage or current at all (i.e., the "test current") and Sivard does not disclose applying a pulse train, much less a pulse train having a pulse frequency substantially higher than the heart rate.

CONCLUSION

For the reasons set forth above, it is submitted that claims 1-11, 13, 15, 16, and 18-30 as set forth herein (all claims) distinguish patentably over the references of record and meet all statutory requirements. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, the Examiner is requested to telephone Thomas Kocovsky at 216.363.9000.

Respectfully submitted,

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